

THE CLAIMS

What is claimed is:

1. A single unit dosage form suitable for oral administration to a human comprising:

5 greater than about 30 mg of an active ingredient, wherein the active ingredient is thalidomide or a pharmaceutically acceptable prodrug, salt, solvate, or clathrate thereof; and
an excipient.

10 2. A single unit dosage form suitable for oral administration to a human comprising:

greater than about 25 mg of an active ingredient, wherein the active ingredient is thalidomide or a pharmaceutically acceptable prodrug, salt, solvate, or clathrate thereof; and

an excipient;

15 wherein the unit dosage form is a capsule.

3. The dosage form of claim 1 or 2 wherein the amount of active ingredient is from about 30 to about 50 weight percent.

4. The dosage form of claim 3 wherein the amount of active ingredient is about 40 weight percent.

20 5. The dosage form of claim 1 or 2 wherein the active ingredient is present in an amount of from about 50 mg to about 200 mg.

6. The dosage form of claim 2, wherein the capsule is size #0, #1, #2, #3, #4, or #5.

25 7. A single unit dosage form suitable for oral administration to a human comprising:

about 200 mg of an active ingredient, wherein the active ingredient is thalidomide or a pharmaceutically acceptable produg, salt, solvate, or clathrate thereof;

about 297 mg of a carrier, diluent or filler, wherein the carrier, diluent or filler comprises pregelatinized corn starch, microcrystalline cellulose, dicalcium phosphate, or a mixture thereof; and

30 about 2.5 mg of magnesium stearate;
wherein the single unit dosage form is a capsule.

8. A single unit dosage form suitable for oral administration to a human comprising:

about 40 weight percent of an active ingredient, wherein the active ingredient is thalidomide or a pharmaceutically acceptable produg, salt, solvate, or clathrate thereof;

about 53 weight percent of a carrier, diluent or filler, wherein the carrier, diluent or filler comprises pregelatinized corn starch or microcrystalline cellulose;

about 4 weight percent surfactant;

about 2 weight percent disintegrant; and

about 1 weight percent lubricant;

wherein the single unit dosage form is a tablet.

9. The dosage form of claim 1, 2, 7, or 8 wherein the active ingredient is thalidomide.

10. A method for treating or preventing leprosy, chronic graft-vs-host disease, rheumatoid arthritis, sarcoidosis, an inflammatory condition, inflammatory bowel disease, or cancer, which comprises administering to a patient in need of such treatment or prevention a single unit dosage form of claim 1, 2, 7, or 8.

11. The method of claim 10, wherein the disease is cancer.

12. The method of claim 11 wherein the cancer is primary or metastatic cancer of the head, neck, eye, mouth, throat, subcutaneous tissue, lymph nodes, esophagus, chest, bone, intestine, lung, colon, rectum, stomach, heart, prostate, breast, ovaries, adrenals, kidney, liver, pancreas, or brain.

13. The method of claim 12 wherein the cancer is colorectal cancer.